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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,219	12/12/2001	Hiroharu Matsuoka	MATSUOKA=18	7465

1444 7590 07/06/2006

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EXAMINER

ROBINSON, BINTA M

ART UNIT PAPER NUMBER

1625

DATE MAILED: 07/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,219

Applicant(s)

MATSUOKA ET AL.

Examiner

Binta M. Robinson

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13-25 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 13-25 and 29 is/are rejected.
- 7) ☒ Claim(s) 6-9, 22, 30 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/27/01; 6/18/02</u> . | 6) <input type="checkbox"/> Other: ____. |

Detailed Action

The objections to claims 1 and 30 in the office action mailed 6/20/05 have been rendered moot in light of applicant's remarks and amendments filed 9/20/05. The 103(a) rejection over Kotake et. al. has been maintained because translations of the priority documents have not been provided to the USPTO and therefore, priority has not been granted and the references below are intervening references. The 102 (b) has been changed to a 102 (e) with the filing date of March 11, 1998 preceding the applicant's filing date of 1/28/00.

(new rejections)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim(s) s, 1,2, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Kotake et. al. (See Reference N). Kotake et. al., discloses for example, the instant compounds, 9, , 88, 89, and 107, 108, and 109. At page 34 and 38, see the instant compounds. Compounds 9, 88, 89, 107, 108, and 109 anticipate the claims because R7 is optionally substituted amino or hydrogen, Cy is phenyl, X is carbonyl, R6 is hydrogen or methyl or amino, R8 is hydrogen or methyl, R9 is optionally substituted phenyl or isopropyl, R10 is hydrogen,

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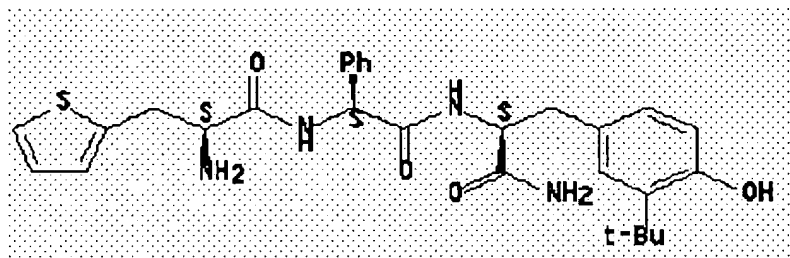
R12 is hydroxyl or alkoxy wherein R16 is methyl, Y is carbonyl, R14 and R15 is hydrogen, R11 is $-\text{CO}-\text{N}(\text{R14})\text{R15}$, R14 and R15 are hydrogen.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 13-21, 24, 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Kotake et. al. (WO 99/09053 A1). At page 36, see compound 54. Compound



anticipates the instant claims

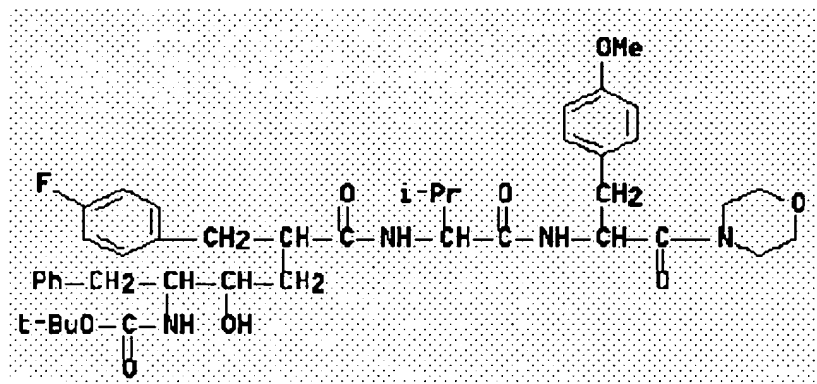
because Cy is thienyl, R7 is amino, X is carbonyl, R9 is phenyl, Y is carbonyl, R11 is amide, R13 is t-Bu, R12 is hydroxyl, R6, R8, R10, R14, R15, R1, R2, R4, R5, R20 are all hydrogen.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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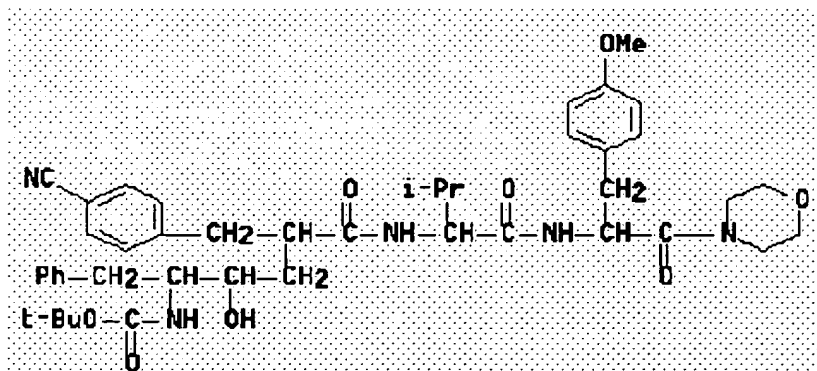
Claims 1-5, 13, 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Bold et. al. (US 5643878). Bold et. al. discloses the instant compound,



The Bold et. al. compound anticipates the claims because R3 is fluorine, Cy is phenyl, R1, R2, R4, R5 are hydrogen, R6 is hydrogen, R7 is -----

CH₂CH(OH)CH(NHC(O)OtBuO(CHCH₂PH), X is carbonyl, R9 is isopropyl, R20 is hydrogen, Y is carbonyl, R10 is hydrogen, R11 is C(O)morpholino, R12 is Ome, R13 is hydrogen. At lines 38 and 39, column 27, see the instant compound.

Claims 1, 2, 7, 9, 13, 15-18 rejected under 35 U.S.C. 102(b) as being anticipated by Bold et. al.. (US 5643878),. Bold et. al. discloses the instant compound,

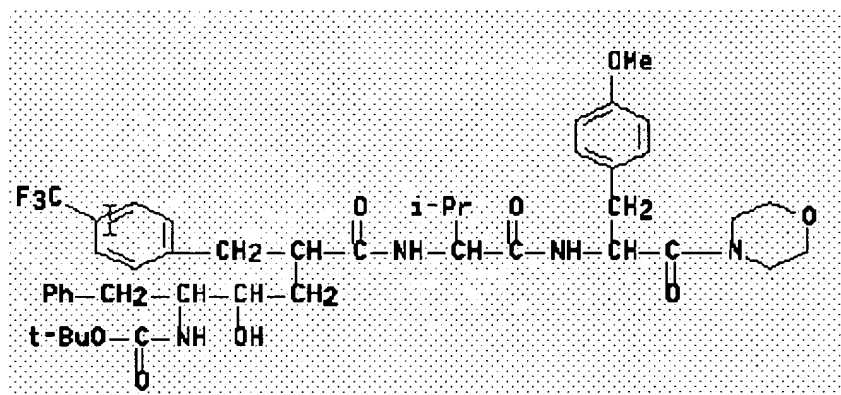


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Which anticipates the claims because R3 is cyano, R7 is -

CH₂CH(OH)CH(NHC(O)OtBuO(CHCH₂PH), X is carbonyl, R9 is isopropyl, R20 is hydrogen, Y is carbonyl, R10 is hydrogen, R11 is C(O)morpholino, R12 is Ome, R13 is hydrogen. At example 58, lines 55-57, see the instant compound.

Claims 1, 2, 13, 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Bold et. al. Bold et. al. discloses the instant compound,



which anticipates the claims

because R3 is F₃C-, Cy is phenyl, R1, R2, R4, R5 are hydrogen, R6 is hydrogen, R7 is -
 -----CH₂CH(OH)CH(NHC(O)OtBuO(CHCH₂PH), X is carbonyl, R9 is isopropyl, R20 is hydrogen, Y is carbonyl, R10 is hydrogen, R11 is C(O)morpholino, R12 is Ome, R13 is hydrogen. At column 27, lines 20 and 21, and at column 116, lines 56-61, see the instant compound

Old rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 13, 14, 15, 16, 17, 18, 19, 20, 21, 23, 24, 25, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable Kotake. (See Reference A, English language equivalent to Reference N).

Kotake et. al. teaches the instant compound as shown in Formula I wherein A is an amino acid residue provided that A binds with $-NR_2-$ to form an amide; R1 is an optionally substituted straight chained or branched alkyl group having 2-7 carbon atoms, R2 is an optionally substituted straight chained or branched alkyl group having 1-3 carbon atoms; R3 is $-CO-R_7$, an optionally substituted straight chained or branched alkyl group having 1-4 carbon atoms, R4 is a straight chained or branched alkyl group having 1-6 carbon atoms, a straight chained or branched alkenyl group having 2-6 carbon atoms, a straight-chained or branched alkynyl group having 2-6 carbon atoms, or the formula 2 which is $C(R_{16})R_{15}R(R_{17})$, R7 is a $-N(R_{12})R_{13}$ or $-OR_{14}$, R12 and R13 which may be the same or different each represent a hydrogen atom, R14 is a hydrogen atom, a straight-chained or branched alkyl group having 1-6 carbon atoms, or a cycloalkyl group having 3-7 carbon atoms; R15 is a hydrogen atom or methyl group; R16 and R17 are taken together and represent a cycloalkyl or cycloalkenyl group having 3-7 carbon atoms. At columns 90-91, see the compound of formula I. The difference between the prior art compound and the instantly claimed compounds is the teaching of a subgenus of compounds versus a genus of compounds. It would have been obvious to one of ordinary skill in the art to select various known radicals within a genus to prepare structurally similar compounds. For instance, see the compound, 108

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at column 36, where a disclosed species is exemplified. Accordingly, the compounds are deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed compounds over those of the generic prior art compounds.

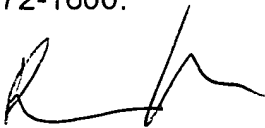
Claims 6-9, 22 and 30 are objected to because they are based on a rejected claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (571) 272-0692. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Thomas Mckenzie can be reached on 571-272-0670.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703)308-4242, (703)305-3592, and (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)-272-1600.



BMR
June 16, 2006

Thomas McKenzie
SPE
AU 1625